



Essential Elements of a Quality Management System

**Monday 9 to Thursday 12
November 2009**

Manchester Marriott Victoria & Albert
Hotel, Manchester, UK

DBA

About This Course

The latest Regulatory Agency thinking on how to ensure the production of safe and effective medicines emphasises on the role of Quality Management Systems (QMS). Deficiencies in this area are often identified during regulatory inspections.

The FDA's 21st Century GMP initiative and subsequent ICH activity demonstrates that the Agencies now agree that effective and robust Quality Systems are essential and can lead to regulatory opportunities. The ICH Q10 guideline 'Pharmaceutical Quality System' was signed off in June 2008, and is expected to be implemented in 2009.

This course is designed to provide you with sound, practical advice on the design and operation of a robust and effective QMS, which will meet the evolving regulatory expectations and add real value to your business.

Whether you already operate a functioning QMS or are currently implementing one in a young company, this course will help you to ensure that your system meets the current and future needs of the regulators and your business!

What You Will Learn

- What a QMS is
- The key components of a QMS
- Best industry practice for key elements of a QMS
- The responsibilities of Management for the QMS
- The relationship between a QMS and GMP
- How to integrate Risk Management into your QMS
- How to utilise QMS across the product life-cycle
- How to document your QMS in a way that will add value to your business and meet regulatory expectations
- How to use Key Performance Indicators to continuously improve your QMS
- The benefits delivered from a modern PQS
- How to and why measure the cost of quality

Who Should Attend

This course is primarily aimed at Quality personnel from...

- Companies with established QMS who wish to understand the latest regulatory position and to improve their systems to ensure they meet the latest regulatory expectations
- Companies with relatively new, developing QMS wishing to improve their systems to add value to their businesses
- Contractors who need to have robust QMS to meet the needs and expectations of a wide range of clients
- Other personnel with a need to understand a QMS would benefit from attending

Course Outline

- **Why every organisation needs an effective QMS**
- **Strengths and weaknesses of the traditional pharmaceutical QMS**
- **The background to the new science and risk-based regulatory paradigm**
 - FDA's 21st century GMP initiative
 - ICH Q8, Q9 and Q10**and how this impacts on QMS design**
- **The key elements of a QMS, including**
 - Documentation
 - Training
 - Validation
 - Deviations/CAPA
 - Change Control
 - Complaints and Recalls
 - People
- **How Quality Risk Management plays a key role in shaping the modern QMS**
- **How a pharmaceutical QMS fits with the ISO9000 standard**
- **Monitoring the effectiveness of the QMS; key performance measures, continuous improvement and costs of quality**
- **The role of management in the QMS**

Discussion and Working Groups

A significant proportion of the course time will be devoted to group work, where delegates have the opportunity, through case studies, to put theory into practice.

Additionally, discussion periods, including a course tutor panel session, provide delegates with an opportunity to obtain answers to their specific questions and concerns.

Your Tutors



Neil Wilkinson

David Begg Associates, UK

Neil joined DBA from AstraZeneca, where he was Senior Director of Global Quality.

A chemist by training, Neil has held roles in QC, QA, Production, Supplier Assurance and International Manufacturing/Compliance. Until recently he was chair of EFPIA's Manufacturing and GMP ad-hoc group and was EFPIA topic leader on the ICH Q10 Expert Work Group.



George Urwin

David Begg Associates, UK

George has 40 years' world-wide experience in the pharmaceutical industry working for a number of major global pharmaceutical and healthcare companies in senior quality management positions.

George's experience has covered API manufacture plus a wide range of pharmaceutical dosage forms and product categories. He has been involved in establishing corporate quality functions developing global quality standards and quality systems, due diligence audits, participating in company mergers and acquisitions, managing major process improvement projects, and operating in 'virtual' environments focusing on outsourcing activities.

George is eligible to act as a QP and has facilitated many regulatory inspections carried out by health authorities including the MHRA and FDA.

Booking Form

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Please reserve me a place on this course...

First/only delegate attending: £2210.00 Plus 15% Value Added Tax (VAT)

Additional delegate(s) from same site: £1768.00 Plus 15% Value Added Tax (VAT)

Includes: tuition, comprehensive course notes, attendance certificate, lunches, refreshments and course dinner on Wednesday evening

Excludes: all hotel accommodation and other dinners (see Hotel Accommodation section)

Course begins at 09.00 on Monday and finishes at 15.00 on Thursday

Please write clearly in BLOCK CAPITALS

Mr/Mrs/Miss/Ms/Dr First Name Surname

Job Title Company

Full Street Address

Post Code

Delegate Tel No Delegate Fax No Delegate Email

Accommodation: I require accommodation (please tick box) YES NO See Hotel Accommodation section for details

Please indicate any special needs (dietary/accommodation):

To guarantee your accommodation reservation, credit card details must be supplied (please write clearly)

Card Number Expiry Date

Sterling cheques, payable on a UK bank to David Begg Associates (York) Ltd, for the full invoiced amount of £2541.50 (first/only delegate) or £2033.20 (additional delegate(s) from same site) (net of ALL bank charges) to be attached to this Booking Form and sent to David Begg Associates (York) Ltd at the address below. Settlement must be received at least 10 working days prior to the course start date. A VAT invoice will be provided. VAT Reg No GB 927 3679 85. Under UK law all applications are subject to VAT irrespective of the country of origin of participants. Most VAT registered companies/organisations can reclaim this tax. Cancellations within 25 working days of the course start date are subject to charges (see Cancellations section). If a Purchase Order number is necessary to effect settlement of our invoice please provide it in the box below.

Purchase Order number

Authorised Signature Date Cheque enclosed

To aid prompt confirmation of your booking, please ensure you submit a completed application form which bears an authorised signature and Purchase Order number

The programme and other information contained in this brochure are correct at the time of printing and are published in good faith. David Begg Associates reserves the right to make any changes which may become necessary.

David Begg Associates (York) Ltd The Georgian House · 22/24 West End · Kirkbymoorside · York · UK · Y062 6AF

Tel: +44 (0) 1751 432999 Fax: +44 (0) 1751 432450 Email: courses@DBA-global.com Website: www.DBA-global.com

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The Venue

The Manchester Marriott Victoria & Albert Hotel stands on the banks of the River Irwell, near the city centre but convenient for Manchester Airport (19km), the city's Piccadilly rail station (3km) and the UK's motorway networks. Recently lovingly restored, this Grade II listed building bears many modern features. The hotel has its own car park and the Living Well Health Club with pool, gymnasium, sauna and steam room is just a few minutes from the hotel. Also nearby are the Imperial War Museum North West, Lowry Museum and Manchester's three theatres. A few minutes' walk takes you to the city's main shopping and eating district.



Hotel Accommodation

- David Begg Associates has a block booking of bedrooms at the Manchester Marriott Victoria & Albert, at the specially negotiated bed and breakfast rate of £123.31 (including VAT) per delegate per night.
- The nights of Sunday 8 to Wednesday 11 November 2009 will usually be reserved.
- Accommodation should only be reserved through us using the Booking Form. Credit card details must be provided to ensure this reservation is kept for you. Please do not contact the hotel directly as this could cause duplicate reservations.
- Your account with the hotel should be settled at check out.
- Any charges made by the hotel as a result of you not taking up your reservation for any reason will remain your responsibility.
- Where at all possible, your booking for accommodation should be received six weeks before the course start date. Places on the course will be available after this time but we cannot guarantee bedroom or rate availability.
- Where no indication is made on the Booking Form, no accommodation will be reserved by us.

To Book on this Course

- Fax the completed and signed form from this brochure to our Course Administrator. Your place will then be confirmed by post and a course fee invoice will be issued.
- Provisional bookings can be made via our website, in the Training Courses section. Online reservations must be confirmed by the completion of a Booking Form (pdf brochure and Booking Form files can be downloaded via the website).
- Make sure you write a Purchase Order number on the Booking Form if this is necessary for settlement of our invoice.
- Reserve a place by telephone or email (contact details are on the Booking Form), confirming as above.

Cancellations

Written cancellations with a full refund will be accepted up to 25 working days before the start date of the course. A cancellation fee of 50% will be payable for cancellations received between 10 and 25 working days before the start of the course. If you cancel within 10 working days of the course start date, full course fees will be chargeable. Delegate substitutions may be made at any time up to the start of the course.